

III. Claim 14 is Patentable Over Droegemueller

Claim 24 was canceled without prejudice, and dependent claim 14 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Droegemueller. Claim 14 incorporates the elements and limitations of independent claim 10 and, therefore, is also believed patentable over Droegemueller in view of the above remarks.

Additionally, Droegemueller fails to disclose, teach or suggest “wherein the step of positioning an inflatable cryogenic element comprises positioning an inflatable cryogenic element on an epicardial surface with a temperature sensor between a portion of the inflatable cryogenic element and a portion of the epicardial surface” as recited in claim 14. It is alleged in the Office Action that it would be obvious to treat epicardial tissues using the device described by Droegemueller on the basis that the cited reference explains that tissues other than the uterus may be treated with the device. However, the Office Action has not established how the device described by Droegemueller, configured to for necrosis of uterus tissue for purposes of female sterilization, is suitable for being positioned on an epicardial surface, which is different than uterine tissue and involves different surgical procedures and considerations. Further, Applicant notes that Droegemueller describes disadvantages, e.g., hospital stay and costs, associated with procedures that involve major surgery and entering the abdominal cavity, and that it is an object of his invention to make available a less expensive sterilization that can be performed without an entire surgical team and support facilities. Droegemueller (col. 1, line 63 - col. 2, line 6).

In view of the above remarks, Applicant respectfully request the rejection of claim 14 under 35 U.S.C. §103(a) be withdrawn.

IV. Claims 11 and 27 Are Patentable Over Droegemueller in view of Joye

Dependent claims 11 and 27 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Droegemueller in view of U.S. Patent No. 6,355,029 to Joye (hereafter referred to as “Joye”). Applicant respectfully traverses the rejection.

In it conceded that Droegemueller fails to disclose “positioning an inflatable cryogenic element carried on a distal portion of a surgical probe on the tissue structure with a temperature sensor carried on an exterior surface of the inflatable cryogenic element between a portion of the inflatable cryogenic element and a portion of the tissue surface” and “at least one temperature sensor on the exterior of the inflatable cryogenic element” as recited in claim 27. Joye is cited for the limited purpose of allegedly disclosing a temperature sensor on an exterior surface of an inflatable cryogenic element. For this purpose, it is apparently alleged that the thermocouple 24 is the “temperature sensor” and the balloon 18 is the “inflatable cryogenic element” as recited in claims 11 and 27. No column/line numbers of Joye are provided in the Office Action so Applicant is not certain which sections or components of Joye are relied upon to reject the claims. Clarification is respectfully requested if Applicant’s understanding is not correct.

Nevertheless, Joye cannot support the rejection since the thermocouple 24 described by Joye is carried by a shaft (which cannot be inflated). Joye (Fig. 1; thermocouple 24 on shaft 20). More specifically, Joye describes a catheter 10 having a catheter body 12, an inflatable balloon 18, a central shaft 20 and a delivery tube 22. Joye (col. 6, lines 1-29; Figs. 1 and 2). Fig. 2 of Joye shows that the shaft 20 and the delivery tube 22 are positioned inside of the catheter body 12. Joye further explains that a thermocouple 24 “is optimally located near the center of the balloon 18” for purposes of measuring the temperature of cryogenic fluid after expansion from the proximal end of the cryogenic delivery tube 22, which is positioned inside the balloon 18 as shown in Fig. 1. Joye (col. 6, lines 30-39; Figs. 1, 8 and 9). More specifically, Fig. 1 of Joye

illustrates a thermocouple 24 that is attached to the shaft 20, which is positioned inside of the balloon 18.

Accordingly, the thermocouple 24 apparently relied upon to reject claims 11 and 27 is positioned on the shaft 20 inside of the balloon 18, as opposed to on an exterior or exterior surface of the balloon. Therefore, Joye cannot disclose "positioning an inflatable cryogenic element carried on a distal portion of a surgical probe on the tissue structure with a temperature sensor carried on an exterior surface of the inflatable cryogenic element between a portion of the inflatable cryogenic element and a portion of the tissue surface" as recited in claim 11 and "at least one temperature sensor on the exterior of the inflatable cryogenic element" as recited in claim 27.

As such, Droegemueller and Joye, individually and collectively, fail to disclose each limitation of claims 11 and 27. Accordingly, the rejection of claims 11 and 27 as allegedly being unpatentable over Droegemueller in view of Joye cannot be sustained on this basis alone.

In addition to these deficiencies, a person of ordinary skill in the art would not combine Droegemueller and Joye given the different configurations and applications of the devices. Droegemueller describes a female sterilization system designed to necrose the functional lining of the uterus. In contrast, Joye describes cryosurgical balloon catheter for treatment of blood vessels. It is well understood that these devices involve surgical procedures given that they involve different parts of the body and are used for different purposes. Further, Droegemueller explains that the bladder 11 should be maintained at about 2 or 3 psi in order to avoid any possible risk of internal injury to the patient, whereas Joye explains that the pressure within the tube 22 of the catheter 10 is substantially higher, i.e., typically in the range of 50-500 psi, and after expansion, nitrogen gas within the balloon near the thermocouple 24 will typically be in the range of 30-100psi. Joye (col. 6, lines 36-50). Thus, Joye describes internal pressures that are

multiples times the pressures described by Droegemueller, which would contradict Droegemueller's explanation that certain pressures are utilized for purposes of avoiding possible risk of internal injury while insuring firm contact with tissue. Given these different structural configurations, operating pressures, and functionality, Applicant respectfully submits that a person of ordinary skill in the art would not combine Droegemueller and Joye.

In view of the above remarks, Applicant respectfully request the rejection of claims 11 and 27 under 35 U.S.C. §103(a) be withdrawn.

CONCLUSION

Applicant respectfully requests entry of this Amendment, and submits that doing so will place the application in condition for allowance in view of the forgoing amendments and remarks. If there are any remaining issues that can be resolved by telephone, Applicant invite the Examiner to kindly contact the undersigned at the number indicated below.

Respectfully submitted,

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